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Translation

PATENT COOPERATION TREATY

PCT/JP2003/013063

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference C1-A0220P	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/013063	International filing date (*day/month/year*) 10 October 2003 (10.10.2003)	Priority date (*day/month/year*) 11 October 2002 (11.10.2002)
International Patent Classification (IPC) or national classification and IPC C07K 16/18, C12P 21/08, A61K 39/395, A61P 35/00, 37/02, 43/00		
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10 October 2003 (10.10.2003)	06 February 204 (06.02.204)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/013063

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 03/13063

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-23	YES
	Claims	1-3	NO
Inventive step (IS)	Claims	5-23	YES
	Claims	1-4	NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims		NO

2. Citations and explanations

Document 1: Blood, 1997, Vol. 90, No. 9, pp. 3629-3639
Document 2: J. Exp. Med., 1995, Vol. 181, No. 6, pp. 2007-2015
Document 3: Int. Immunol., 1998, Vol. 10, No. 9, pp. 1347-1358
Document 4: Mol. Immunol., 1999, Vol. 36, No. 6, pp. 387-395
Document 5: Biochem. Biophys. Res. Commun., 1999, Vol. 258, No. 3, pp. 583-591
Document 6: Blood, 1999, Vol. 93, No. 11, pp. 3922-3930

Claims 1 to 3

Claims 1 to 3 lack novelty and do not involve an inventive step in the light of documents 1 to 3 cited in the international search report.

Document 1 indicates monovalent Fab' fragments from an antibody against the α1 domain of HLA class IA molecules from humans. Therefore, the invention that is indicated in document 1 cannot be differentiated from the invention that is set forth in claims 1 to 3 of the present application.

Document 2 indicates Fab fragments from the antibody (RE2) against the α2 domain of HLA class IA molecules from mice. Therefore, the invention that is indicated in

document 2 cannot be differentiated from the invention that is set forth in claims 1 to 3 of the present application.

Document 3 indicates monovalent Fab fragments from an antibody against the α3 domain of HLA class IA molecules. Therefore, the invention that is indicated in document 3 cannot be differentiated from the invention that is set forth in claims 1 to 3 of the present application.

Claims 1 to 4

Claims 1 to 4 do not involve an inventive step in the light of documents 4 to 6 cited in the international search report. Documents 4 to 6 indicate the production of humanized antibodies from anti-HM1.24 antibodies that are obtained by immunizing Balb/c mice using human myeloma cells.

The feature of degrading an antibody is well known in the technical field in question; therefore, it would be easy for a person skilled in the art to produce antibody fragments by degrading the anti-HM1.24 antibodies that are indicated in documents 4 to 6.